



Case Docket No. ACADIA.031A

Date: July 15, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)

Weiner, et al.

Appl. No.

10/761,787

Filed

January 21, 2004

For

USE OF N-

DESMETHYLCLOZAPINE TO

TREAT HUMAN

NEUROPSYCHIATRIC DISEASE

Examiner

Unknown

Group Art Unit:

1614

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, on

July 15, 2004

(Date)

Sam K. Tahmassebi, Reg. No. 45,151

TRANSMITTAL LETTER

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application are:

- (X) A Supplemental Information Disclosure Statement.
- (X) A PTO Form 1449 with seven (7) references.
- (X) The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.
- (X) Return prepaid postcard.

Sam K. Tahmassebi Registration No. 45,151 Attorney of Record Customer No. 20,995 (619) 235-8550 Docket No.: ACADIA.031A

JUL 1 9 2004

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicant

Weiner, et al.

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Unknown

Group Art Unit

1614

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Enclosed is form PTO-1449 listing seven references that are also enclosed.

This Information Disclosure Statement is being filed before the mailing date of a final action under 37 C.F.R. § 1.113 and before the mailing date of a Notice of Allowance under § 1.311. A certification under 37 C.F.R. § 1.97(e) is set forth below. Thus, no fee is required as set forth in 37 C.F.R. § 1.97(c).

EXPLANATION UNDER 37 C.F.R. § 1.98(a)(3)(i)

The relevance of French Patent FR 51 F is that it depicts N-desmethylclozapine in Table 2, Example 9 and contains a statement on page 5, left hand column, that the International Search Authority stated disclosed a tablet preparation that was "a neuroleptic useful in the treatment of psychosis."

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Docket No. ACADIA.031A Customer No. 20,995

CERTIFICATION UNDER 37 C.F.R. § 1.97(e)(1)

I hereby certify that each item of information contained in this Statement was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this Information Disclosure Statement.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated:

By:

Sam K. Tahmassebi

Registration No. 45,151

Attorney of Record

Customer No. 20,995

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SHEET 1 OF	-

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRAPETERS OFFICE	ATTY. DOCKET NO. ACADIA.031A	APPLICATION NO. 10/761,787
BY APPLICAN JUL 1 9 2004	APPLICANT Weiner, et al.	
(USE SEVERAL SHEETS IF NESSARY)	FILING DATE January 21, 2004	GROUP 1614

				FOREIGN PATENT DOCUMENTS				
EXAMINER		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
INITIAL							YES	NO
	1	WO 02/060870	08/08/02	WIPO				
	2	FR 51	04/06/64	France			-	

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)						
	3	Özdemir, V., et al., "CYP1A2 Activity as Measured by a Caffeine Test Predicts Clozapine and Active Metabolite Norclozapine Steady-State Concentration in Patients With Schizophrenia," <i>Journal of Clinical Psychopharmacology</i> , 21:4(398-407), August 2001.					
	4	Spina, E., et al., "Effect of fluoxetine on the plasma concentrations of clozapine and its major metabolites in patients with schizophrenia," <i>International Clinical Psychopharmacology</i> , 13:141-145, 1998.					
	5	Sur, C., et al., "N-desmethylclozapine, an allosteric agonist at muscarinic 1 receptor, potentiates N-methyl-p-aspartate receptor activity," <i>Proceedings of the National Academy of Sciences of the United States of America</i> , 100:23(13674-13679) Nov. 11, 2003.					
	6	Weigmann, H., et al., "Does the pharmacologically active N-demethylated metabolite of clozapine pass the blood-brain barrier?" <i>Pharmacopsychiatry</i> , and "20 th Symposium of AGNP, Nuremberg, Germany," 30:5(233), September 1997.					
	7	Young, C., et al., "Effects of Desmethylclozapine on Fas Protein Expression in the Forebrain: In Vivo Biological Activity of the Clozapine Metabolite,", <i>Neuropsychopharmacology</i> , 19:1(99-103) 1998.					

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EXAMINER

DATE CONSIDERED